4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6730]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Malfunction Summary Reporting Program for Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0437. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Reporting: Electronic Submission Requirements

OMB Control Number 0910-0437--Extension

The information collection associated with 21 CFR part 803 is approved under OMB control number 0910-0437. We request revision of the information collection approval as described in this document.

In the *Federal Register* of December 26, 2017 (82 FR 60922), FDA published a notification and request for comments entitled "Center for Devices and Radiological Health; Medical Devices and Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers" (the notification) which, among other things, proposed a program for manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form--the Voluntary Malfunction Summary Reporting Program. The proposed program would permit manufacturers of devices in certain product codes to report malfunctions for those devices on a quarterly basis and in a summary format (instead of reporting them as individual, 30-day reports), subject to certain conditions. Therefore, we have added a line item to the reporting burden table in OMB control number 0910-0437, "Medical Device Reporting: Electronic Submission Requirements," for the proposed Voluntary Malfunction Summary Reporting Program.

FDA believes that submission of voluntary summary reports in the format described in this document would provide the most compact and efficient reporting mechanism for streamlining malfunction reporting that still provides sufficient detail for FDA to monitor devices effectively. The proposed Voluntary Malfunction Summary Reporting Program is meant to streamline the process of reporting malfunctions. It does not change regulatory requirements for MDR-related investigations or recordkeeping by manufacturers. The proposed program would neither apply to importers or device user facilities, nor affect requirements under part 803 for importers or device user facilities. The proposed program would not apply to reportable death or serious injury events, as described in section III.A of the notification (82 FR 60922 at 60924). In addition, the reporting requirements at § 803.53, which require a 5-day report to be filed at the written request of FDA or if a manufacturer becomes aware of an MDR reportable event that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, would continue to apply to manufacturers participating in the proposed program. The conditions of the proposed Voluntary Summary Malfunction Reporting Program would also require manufacturers to submit individual malfunction reports in certain circumstances (see section III.A of the notification). These factors were considered in determining the revised burden estimates described in table 1.

In the *Federal Register* of December 26, 2017 (82 FR 60922), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment related to the information collection, that stated that the average burden on manufacturers per response of 6 minutes appears to be a very low estimate.

FDA disagrees with this comment. The estimation of time is the amount of time needed to submit a summary malfunction report. It is essentially the same amount of time needed to

submit an individual report because the event narrative should be the same, with the exception of one additional line that is entered that indicates the number of adverse events represented by the report. It does not include the time needed to investigate the issue. Manufacturers have 120 calendar days from the date they become aware of a reportable malfunction to submit a summary malfunction report that is allowed as part of this voluntary reporting program.

For the convenience of the reader, we have noted below the information collection line-items (ICs) that we anticipate would be affected by the Voluntary Malfunction Summary Reporting Program. While the other ICs from OMB control number 0910-0437 are not affected by the Voluntary Malfunction Summary Reporting Program, for consistency and accuracy, we have adjusted the respondent estimates for the ICs using more recent data.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity/CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Exemptions--803.19 [2]		85	4	340	1	340
User Facility Reporting--803.30 and 803.32 [2]		520	10.06	5,232	0.35	1,831
User Facility Annual Reporting--803.33 [2]	3419	159	1	159	1	159
Importer Reporting, Death and Serious Injury--803.40 and 803.42 [2]		578	1	578	1	578
Manufacturer Reporting--803.50 through 803.53 [3]		1,240	272.50	337,900	0.10	33,790
Voluntary Malfunction Summary Reporting Program [3]		1,240	54.47	67,546	0.10	6,755
Supplemental Reports--803.56 [3]		1,050	128.71	135,148	0.10	13,515
Total						56,968

[1] There is no change to the capital costs or operating and maintenance costs associated with the revision of the collection of information.
[2] This IC has been adjusted based on calendar year (CY) 2016 data; however, there is no program change to this IC.
[3] This IC revises OMB control number 0910-0437 to reflect the Voluntary Malfunction Summary Reporting Program.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
[2] MDR Procedures--803.17	1,240	1	1,240	3.3	4,092
[2] MDR Files--803.18	1,240	1	1,240	1.5	1,860

Table 2.--Estimated Annual Recordkeeping Burden[1]

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Total					5,952

[1] There is no change to the capital costs or operating and maintenance costs associated with the revision of the collection of information.
[2] This IC has been adjusted based on CY 2016 data; however, there is no program change to this IC.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[3]
Importer Reporting, Death and Serious Injury--803.40 and 803.42 [2]	578	25	14,450	0.35	5,058

[1] There is no change to the capital costs or operating and maintenance costs associated with the revision of the collection of information.
[2] This IC has been adjusted based on CY 2016 data; however, there is no program change to this IC.
[3] Number has been rounded.

For consistency and accuracy, we have adjusted the respondent estimates for all the ICs from OMB control number 0910-0437, including those that are not affected by the Voluntary Malfunction Summary Reporting Program, to reflect more recent data from calendar year (CY) 2016 (the currently approved estimates are based on CY 2006-2009 data). This adjustment, along with the revisions for the Voluntary Malfunction Summary Reporting Program increases the estimated total burden of OMB control number 0910-0437 by 21,532 hours (currently approved for 46,446 hours; requesting 67,978 hours).

We have added the new burden estimate for the Voluntary Malfunction Summary Reporting Program. This increases the reporting burden estimate by 6,755 hours.

We have revised the burden estimates for "Manufacturer Reporting" and "Supplemental Reports" to update the respondent estimates using more recent data, as described above, and to reflect the revisions resulting from the availability of the Voluntary Malfunction Summary Reporting Program. We believe the availability of the summary reporting option for manufacturers of certain devices would cause a decrease in the number of individual manufacturer reports for malfunctions submitted under §§ 803.50 and 803.52. However, because

we also adjusted the respondent estimates for the ICs using more recent data from CY 2016, the estimated burden for these ICs is an increase of 12,139 hours from the currently approved burden estimates (the previous estimate based on CY 2006-2008 data was 35,166 hours for these ICs only). We attribute the increase to the increase in the number of submissions we received in recent years, rather than the revisions related to the Voluntary Malfunction Summary Reporting Program.

Dated: June 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-12336 Filed: 6/7/2018 8:45 am; Publication Date: 6/8/2018]